

# Notice of Allowability

Application No.

09/548,290

Examiner

Anne Marie S. Wehbe

Applicant(s)

SASAKAWA ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 9/6/05.
2. ☒ The allowed claim(s) is/are 38-53.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### EXAMINER'S AMENDMENT

Applicant's amendment and response received on 9/6/05 has been entered. Claims 1-37 are canceled and new claims 38-53 have been added. Claims 38-53 are therefore pending in the instant application.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas Cunningham on 9/29/05.

The application has been amended as follows:

1. Claim 46 has been rewritten as follows:

Claim 46. A method of producing the NC/Nga mouse of Claim 38, comprising:

maintaining a NC/Nga mouse in a specific pathogen free environment and sensitizing the ear(s) of the mouse with the mite extract by multiple sequential injections of mite antigen over a period of 18 days or less in a pathogen-free environment.

Following entry of this examiner's amendment, claims 38-53 are allowable.

The following is an examiner's statement of reasons for allowance. The previous rejections of claims 29-30 and 32-37 under 35 U.S.C. 103 have been rendered moot by applicant's cancellation of these claims. Further, the previous grounds of rejection under 103 do not apply to new claims 38-53 in view of the added limitations in the claims that the mice were sensitized with mite extract by multiple sequential injections of mite antigen over a period of 18 days or less, and by the added limitation that mice made using the claimed methods exhibit at least one symptom of severe dermatitis in a shorter period of time than conventional NC/Nga mice, or develop dermatitis lesions sufficiently severe for evaluating the effectiveness of a medicine by day 18. The declaration by Dr. Sakuma under 37 CFR 1.132 filed on 12/13/04, of record, provides evidence that mice made using the methods as claimed have properties which would have been unexpected in view of the prior art of record. As the new claims include the specific method used and the unexpected properties referred to in the declaration by Dr. Sakuma, the prior art of record does not apply since the prior art of record does not teach multiple sequential administration of mite antigen, and further does not provide a reasonable expectation that mice prepared as claimed would exhibit at least one symptom of severe dermatitis in a shorter period of time than conventional NC/Nga mice, or develop dermatitis lesions sufficiently severe for evaluating the effectiveness of a medicine by day 18. Thus, new claims 38-53 are considered free of the prior art of record.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

